

Lesson 10

Ethical Issues

Instructor's Guide Form

Lesson Title: Ethical issues

Lesson Goal: For each learner to become knowledgeable of ethical issues in public health surveillance and to apply those issues through class exercises

Lesson Objectives: By the end of this lesson, the learner will be able to:

- 1) describe the role of ethics in public health
- 2) discuss moral principles in research and their application to public health surveillance
- 3) discuss the ethical responsibilities in surveillance
- 4) describe relationships in surveillance and their associated ethical obligations
- 5) describe ethical issues in surveillance:
 - beneficence dissemination
 - nonmaleficence confidentiality
 - protection of privacy veracity
 - informed consent
 - social environment
 - disclosure
- 6) apply ethical concepts and issues to a case study

Lesson 10

Ethical Issues

Instructor's Guide Form (continued)

Equipment and Materials Needed:

- Overhead projector
- Transparencies #10.1 - #10.14
- Flip chart for exercise

Time Required: 60 minutes

Synopsis of Lesson: This lesson describes ethical issues involved in conducting public health surveillance. Learners will have an opportunity to apply these issues through group discussions and an exercise.

Adult Education Application: Facilitating group discussion can be one of the more enjoyable parts of the instructional process. A well facilitated group discussion can encourage adult learners to interact with each other and the material at the same time. For adult learners, this can satisfy their need to apply the material to their own reality.

Group discussions are best used with questions posed to the learners that do not have right or wrong responses. In this chapter on ethics, there are many opportunities for the instructor to pose to the learners ethical dilemmas regarding the use or misuse of surveillance data (see section III-B-2). The role of the instructor is to set general rules for the discussion, encourage the learners to participate, reiterate statements from the learners' comments, add clarifying insights, control the amount of air time used by any one learner, and summarize the discussion points at the end of the allotted time.

Lesson 10

Ethical Issues

Topical Outline

I. Introduction to ethics

- A. Ethics
- B. Ethical code
- C. Ethical obligations
- D. Public health ethics may conflict with ethics of clinical medicine
- E. Ethics in public health
- F. Theories regarding ethics

II. Moral principles in clinical medicine and research

- A. Basic moral principles which apply to public health surveillance
- B. Other ethical principles

III. Conflicts and sanctions

- A. Conflicts among ethical principles
- B. Types of contact involved in surveillance

IV. Relationships in surveillance and their associated ethical obligations

- A. Surveillance practitioners and society at large
- B. Methodological and analytic scrutiny
- C. Interpretation and recommendation
- D. Report of findings

Lesson 10

Ethical Issues

Topical Outline

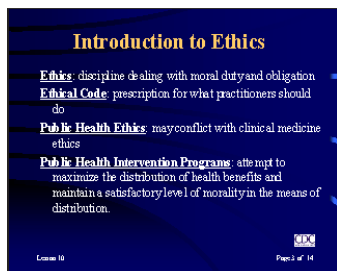
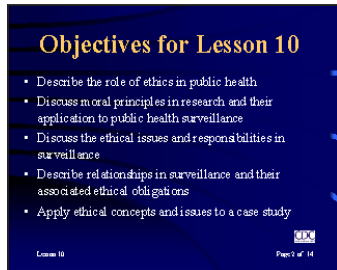
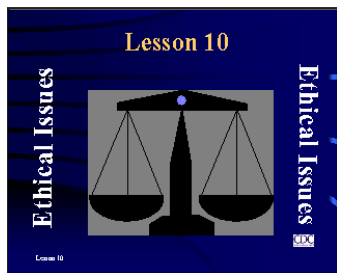
V. Investigators and subjects

- A. Beneficence
- B. Nonmaleficence
- C. Protection of privacy
- D. Informed consent
- E. Disclosure, dissemination, and confidentiality
- F. Veracity
- G. Investigators and persons in subjects' social environments
- H. Surveillance and the public health community

VI. Clinicians and the public health community

- A. View of ethics
- B. Ethical checklist for public health surveillance
- C. Exercise

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Lesson 10

Ethical Issues

Content Outline

Lesson Objectives:

- Describe the role of ethics in public health
 - Discuss moral principles in research and their application to public health surveillance
 - Discuss the ethical issues and responsibilities in surveillance
 - Describe relationships in surveillance and their associated ethical obligations
 - Apply ethical concepts and issues to a case study
-

I. Introduction to ethics

A. Ethics

1. the discipline dealing with what is good and bad or right and wrong
2. dealing with moral duty and obligation

B. Ethical code

1. is not a description of what practitioners (and others) actually do
2. is a prescription for what practitioners should do

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C. Ethical obligations

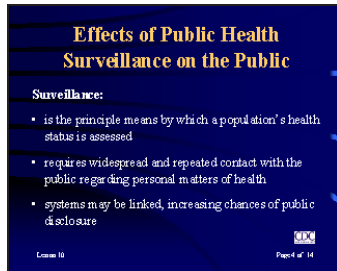
1. derive from moral values
 - a. example: Golden Rule
(may want to give example from other cultures)
 - b. values shared by broader society
2. are not derived from scientific principles
3. ethical decisions require an understanding of the objectives, current issues, and methods of the scientific disciplines to which they refer

D. Public health ethics may conflict with ethics of clinical medicine

1. example: patient confidentiality - when patient's condition threatens the health of others
2. example: when demands of public health compromise the rights of individuals - quarantine
3. example: when mass vaccination is required for public health despite the personal objections of individual patients
4. the practice of public health generally assumes that individual rights may be ethically superseded in the pursuit of public well-being and a greater public good

E. Ethics in public health

1. epidemiologists and ethicists have recently collaborated in the formulation of ethical principles for epidemiology (Soskolne CL. Ethical decision-making in epidemiology: The case study approach. (*J. Clin Epidemiol* 1991;44 (Supp 1): 125S-130S).



2. ethical issues confronting public health surveillance are similar to those of epidemiology
 - a. examples in lesson draws on experience in epidemiologic research
 - b. use of examples from epidemiologic research are meant to be illustrative of the ethical issues, not to suggest that they are examples of surveillance

3. effects of public health surveillance on the public

- a. surveillance is the principal means by which the health status of the population is assessed
- b. surveillance can be used to identify problems, indicate solutions, plan interventions, and monitor change
- c. public health surveillance commonly requires widespread and repeated contact with the public it serves regarding basic and often personal matters of health and exposures to risk factors
- d. surveillance systems may be linked with other systems
 - 1) requires compatible identifiers of individual records
 - 2) systems may be shared among researchers or public health officials which will increase chances of public disclosure

F. Theories regarding ethics

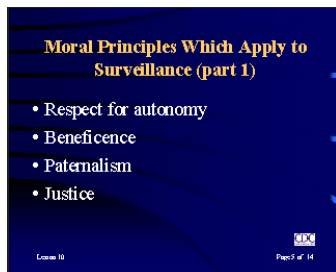
1. utilitarian
 - a. ethical actions are those that most effectively distribute valued goods within the population
 - b. sometimes equated with “the end justifies the means”

2. deontologists
 - a. certain principles, such as honesty, are fundamental
 - b. the ends do not justify the violation of fundamental principles
3. public health intervention programs commonly combine both theories
 - a. attempt to maximize the distribution of health benefits
 - b. maintain a satisfactory level of morality in the means of distribution

II. Moral principles in clinical medicine and research

A. Basic moral principles which apply to public health surveillance

1. respect for autonomy
 - a. “autonomous actions and choices should not be constrained by others”
 - b. basic to this principle is self-determination and voluntary action
2. beneficence
 - a. one should act to enhance the welfare of others
 - b. first tenet of beneficence
 - 1) nonmaleficence
 - a) avoiding acts that might harm others
 - b) sometimes viewed as a separate principle
 - 2) in order to benefit others, one must at least avoid doing them harm



3. paternalism

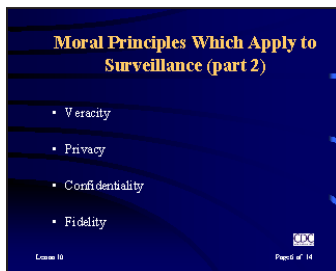
- a. active pursuit of another person's well-being (as perceived by the pursuer), independent of, and sometimes contrary to, that person's express wishes
- b. may be regarded as a form of beneficence
- c. notion may be broadened from protection of a person against harm to himself to include threatened harm to others
- d. paternalism conflicts with respect for autonomy
- e. becomes useful when a person's capacity for autonomy is compromised (as may occur in sickness) or when personal autonomy may seriously compromise the well-being of others

4. justice

- a. promotes the equitable distribution of burdens and benefits in society
- b. there is no agreed-upon definition of equity
- c. range includes an equal share for each person, each according to need, each according to effort, each according to societal contribution, or each according to presumed merit

B. Other ethical principles

- 1. these principles are regarded as independent by some ethicists and as derivative from more basic principles by other ethicists
- 2. veracity
 - a. the duty of full disclosure of relevant information
 - b. often considered a duty of clinicians or researchers
 - c. may also be a duty of patients or subjects



3. privacy

- a. the duty to respect a person's right "of determining to what extent his thoughts, sentiments, and emotions shall be communicated to others"
- b. includes protection from unwanted intrusions, and from the divulgence of personal information to others
- c. the right to privacy may derive from respect for autonomy

4. confidentiality

- a. the duty not to disclose information about individuals without their consent
- b. may be seen as a principle following privacy

5. fidelity

- a. the duty to keep promises and maintain contracts
- b. commonly applied to the relationship between physician and patient

III. Conflicts and sanctions

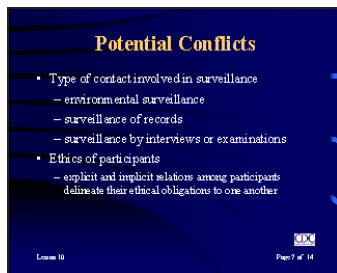
A. Conflicts among ethical principles

- 1. commonly occur
(example: paternalism vs. respect for autonomy)
- 2. attempts to prescribe principles of conflict resolution emphasize that decisions should be accompanied by justification of the choice

3. in contrast to institutions of clinical medicine, institutions of public health do not license practitioners
 - a. rare, but could be taken to court for negligence
 - b. public health practitioners are not sued for malpractice
 - c. informal sanctions occur but have not been systematically described
 - 1) avoidance of unscrupulous colleagues
 - 2) loss of one's job
4. some epidemiologists have recently proposed an ethical duty to monitor and address the unethical practices of their colleagues
5. some aspects of confidentiality are governed by law such as violations of confidentiality by surveillance personnel

B. Types of contact involved in surveillance

1. varies by form of surveillance
 - a. environmental surveillance
 - 1) involves contact with animals or the physical environment rather than with humans
 - 2) example: environmental lead
 - 3) example: rates of infection of ticks with the agent of Lyme disease
 - b. surveillance of records
 - 1) requires indirect contact
 - 2) example: hospital records
 - 3) example: death certificates



- c. surveillance by interviews or examinations - human contact
 - 1) requires face-to-face contact
 - 2) example: household interviews
 - 3) example: physical examinations
 - 4) example: surveys
 - a) example: Health Interview Survey
 - b) example: National Health and Nutrition Examination Survey
 - c) example: Vital Statistics System of CDC's National Center for Health Statistics
 - d) U.S. Census
 - e) do not meet stringent objectives of public health surveillance
 - f) entail the collecting of personal information on individuals

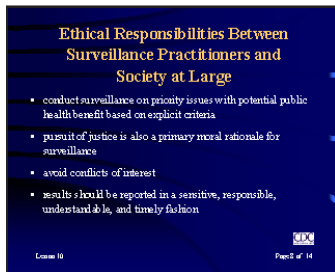
2. ethics of those participants

- a. collection of public health information may involve participation of many individuals and institutions
- b. potential participants
 - 1) investigator
 - 2) subjects of surveillance
 - 3) persons in the immediate social environment of study subjects
 - 4) investigator's colleagues
 - 5) broader public health community
 - 6) clinicians
 - 7) society at large
- c. explicit and implicit relations among participants delineate their ethical obligations to one another

- d. Handout: Table 9-1 from text (page 179)
- 1) *facilitate class discussion of handout - Ethical responsibilities in surveillance - participants and duties*
 - 2) *could begin with only headings (Responsibility, Investigator as well as the participants) on transparency and encourage through instructor facilitated discussion to fill in the class responsibilities which each participant has towards other participants in surveillance*

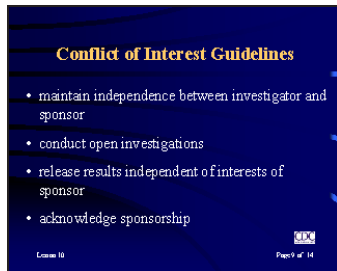
IV. Relationships in surveillance and their associated ethical obligations

A. Surveillance practitioners and society at large



1. the practice of public health may be regarded as one means by which a society addresses issues of well-being in the population
2. public health practitioners retain an essential connection with society at large
3. ultimately, public health practitioners are supported by and act at the behest of their public constituency
4. assumption is that as they pursue and achieve public interests, they should be supported by society in their work

5. as agents of public welfare, public health practitioners have several ethical responsibilities
 - a. choice of surveillance topics
 - 1) practitioners should conduct surveillance on priority issues with potential public health benefit
 - 2) pursuit of justice is also a primary moral rationale for surveillance
 - 3) judgments of priority and potential benefit should be based on explicit criteria
 - 4) surveillance data facilitate the determination of priority issues; for example, magnitude and location of health problems in the population
 - b. avoidance of conflicts of interest
 - 1) virtually all epidemiologic research is sponsored, and few if any research sponsors, public or private, are disinterested in the outcome of their epidemiologic research
 - 2) practitioners of surveillance must assure that surveys are conducted to answer scientific or public health questions effectively, rather than to serve the interests of financial and institutional sponsors or to prove personal preconceptions for example, practitioners must assure the populations surveyed and questions asked are appropriate to assess the issues considered and not to find “results” desired by a sponsor



- 3) guidelines for avoiding conflicts of interest
 - a) facilitate group discussion
 - b) the investigator's independence from the sponsor must be maintained in the design, conduct, and reporting of epidemiologic (and surveillance) results
 - c) written agreement between the investigator and the sponsor may increase the likelihood of independence
 - d) investigations should not be conducted in secrecy and results should be published in a timely fashion
 - e) decisions on release and publication of results should not be influenced by the interests of sponsors
 - f) all sponsorship should be acknowledged
 - g) decisions regarding the dissemination and publication of results should be made by the investigator rather than the sponsor
- 4) Bond says that certain private industries may have an ethical obligation to monitor the effects of their activities
 - a) monitor exposure of employees to potentially harmful agents
 - b) monitor health of employees

- 5) Rothman argues that it is unethical to judge the results of investigations simply on the basis of sponsorship and that investigations should be judged by the quality of the work involved

B. Methodological and analytic scrutiny

1. principle of beneficence requires that one choose the most feasible method of investigation
2. one must appropriately analyze results
3. to do this requires knowledge of scientific methods

C. Interpretation and recommendation

1. principle of beneficence requires that surveillance data not be archived
2. surveillance data must be interpreted and used to assess and address public health problems

D. Report of findings

1. principle of beneficence requires that surveillance results be reported in specific fashion
 - a. understandably
 - b. sensitively
 - c. responsibly
 - d. in a timely fashion
 - e. with scientific objectivity and caution
 - f. with appropriate confidence
 - g. note appropriate doubt

2. epidemiologists should carefully avoid being placed in a situation in which their results might be suppressed or inappropriately edited by either internal or external influences
3. arguments regarding reporting of findings
 - a. some researchers have argued that epidemiologists should be advocates for the positions firmly supported by their data
 - b. some researchers have asserted that epidemiologists are legitimate expert witnesses
 - c. practitioners of surveillance must be free of internal or external constraints
 - d. practitioners must be able to present the results of their work objectively
 - e. such issues should be addressed in the evaluation of surveillance systems such as when new conditions are added to notifiable-disease lists

V. Investigators and subjects

A. Beneficence

1. surveillance subjects do not usually benefit directly from surveillance
2. benefit may accrue as a side-effect
 - a. example: when surveillance subjects are give physical examinations
 - b. example: when a discovery made by surveillance serves a health need of a surveillance subject



3. when an adverse health condition is determined in the course of surveillance it is the responsibility of the investigator to provide the surveillance subject with timely information about the discovered condition
4. at the local level, subjects can most directly benefit from surveillance by prompt action to investigate epidemics, initiate treatment, or prevent spread

B. Nonmaleficence

1. surveillance subjects must not be harmed in the course of the surveillance program
2. when invasive procedures are used, care must be taken that subjects do not suffer undue reactions
 - a. physical procedures
 - b. psychological procedures
3. cultural sensitivity
 - a. may be a component of beneficence, nonmaleficence, and autonomy
 - b. may enhance the effectiveness of the investigation
 - c. important during the course of surveillance
 - d. important in the appropriate reporting of results
4. participant compensation
 - a. nonmaleficence may require that survey participants be compensated
 - b. compensation should at least cover costs of participants
 - 1) transportation
 - 2) lost work time
 - 3) child care
 - c. additional compensation may increase the participation (a pragmatic rather than an ethical justification for payment)

C. Protection of privacy

1. requires restraint in intrusion
2. requires restraint in the disturbance of persons in their private lives
3. requires assurance that once information (or a specimen) has been collected it will not be distributed to others in a form that identifies the surveillance subject
4. conditions that must be satisfied in order to justify invasion of privacy by surveillance investigators (Beauchamp et al)
 - a. invasion of privacy must be a necessary aspect of the investigation
 - b. there is no reason to suspect that subjects of the investigation will be placed at substantial risk (of being fired or divorced)
 - c. the research must have potential social benefit
5. Public Law 93-579, the Privacy Act
 - a. the privacy of an individual is directly affected by the collection, maintenance, use, and dissemination of personal information by Federal agencies
 - b. the right to privacy is a personal and fundamental right protected by the Constitution of the United States
 - c. in order to protect the privacy of individuals identified in information systems maintained by Federal agencies, it is necessary and proper for the Congress to regulate the collection, maintenance, use, and dissemination of information by such agencies

- d. in the U.S., public health surveillance activities conducted under the auspices of the Executive Branch are regulated by the Public Health Service Act and the Privacy Act of 1974
 - 1) includes the Department of Health and Human Services
 - 2) includes the Bureau of the Census
 - 3) both acts regulate contractors of federal agencies as well as the agencies themselves
 - 4) regulations apply to institutions as well as to individuals surveyed
 - 5) records without identifiers are exempt from these regulations
- e. Privacy Act restricts surveillance information that may be collected by stipulating that records may contain only “such information about an individual as is relevant and necessary to accomplish a purpose of the agency.”
- f. prohibits use of surveillance for any purpose other than the purpose for which it was supplied unless consent has been given
- g. individual rights provided by Privacy Act
 - 1) the right to obtain their own records
 - 2) the right to correct errors in the record
 - 3) the right to receive an accounting of how the record has been disseminated
- h. exemptions to individual access
 - 1) includes use of records maintained for statistical purposes only (rather than for administrative use)
 - 2) census information is exempt
 - 3) exemptions must meet specific criteria and must be published in the *Federal Register*

- i. Privacy Act and federal agencies
 - 1) federal agencies must train and regulate personnel with access to record systems
 - 2) federal agencies must maintain physical means of protecting records from unwarranted access
 - 3) agencies must describe their record systems
 - 4) agencies must report procedures used to comply with requirements in the *Federal Register*
- j. criminal penalties and fines may be imposed on persons who violate the Privacy Act

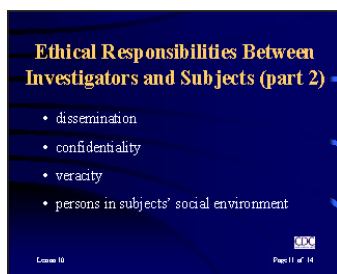
D. Informed consent

- 1. is a requirement based on respect for autonomy
- 2. must be attained primarily in the context of surveys and studies
- 3. Privacy Act
 - a. regulates informed consent procedures by which data are collected
 - b. regulates the matters of confidentiality involved in the dissemination of data that have been collected
 - c. requires that potential participants in record systems be informed of certain points
 - 1) the authority under which the data are collected
 - 2) the purposes of the information
 - 3) the routine uses of the information
 - 4) the consequences of not participating

4. informed consent is required for “establishments” and for individuals
5. elements to be included in informed consent
 - a. reasonable disclosure of the goals and uses of the study (or surveillance activity)
 - b. evidence of comprehension on the part of prospective participants
 - c. voluntaryism on the part of prospective participants
 - d. competence on the part of prospective participants
6. possible harm of the surveillance should be explained to prospective participants
7. Feinlieb argues “the first responsibility of the epidemiologist to the subject is to be clear about the objectives of the study”
 - a. although goals may be complex to explain or disclosure may bias, participants should not be deliberately misled
 - b. paternalistic principle may compromise the participant’s autonomy
8. *Handouts and discussion - examples of informed consent forms from the instructor's own institution can be used*

E. Disclosure, dissemination, and confidentiality

1. Privacy Act forbids the disclosure of information in which individual identity is ascertainable, unless subject consents
 - a. protects confidentiality
 - b. affects dissemination of surveillance findings



2. Freedom of Information Act (FOIA)

- a. records protected by the Privacy Act are exempt from FOIA requests
- b. FOIA exempts “personal and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy”
- c. commonly exempts matters “specifically exempted from disclosure by statute”
- d. federal surveillance data are exempt from subpoena and may be explicitly exempted by authorization of the Secretary of HHS

3. dimensions of disclosure

- a. exact and approximate disclosure
 - 1) exact disclosure indicates a precise (numerical) value of some characteristic associated with an individual
 - 2) approximate disclosure indicates a range of values associated with an individual
- b. probability-based and certainty disclosure
 - 1) probability-based indicates the likelihood (less than 100%) that some characteristic is associated with an individual
 - 2) certainty disclosure indicates (with 100% likelihood) that the characteristic is associated with the individual
- c. internal and external disclosure
 - 1) internal disclosure associates an individual with a characteristic on the basis of evidence found within a particular study or survey
 - 2) external disclosure associates individuals and characteristics by linking studies or surveys

4. types of breaches of confidentiality
 - a. breach for welfare of others
 - 1) information collected in confidence by a clinician or public health practitioner should be divulged if the information substantially threatens the welfare of another person
 - 2) divulging information need not reveal the identity of the first individual, but such revelation may be unavoidable; this commonly occurs in contact tracing for STDs
 - 3) public health responsibilities of clinicians and public health practitioners may override the duties of confidentiality to individual patients and surveillance subjects
 - b. unethical breach of confidentiality
 - 1) revelation of information serves no public health purpose
 - 2) identity of an individual serves no public health purpose
5. techniques to mitigate the likelihood of disclosure
 - a. small samples (<10%) hamper efforts to identify individuals in a population
 - b. deliberate creation of errors or an imputation rather than a true observation
 - c. incompleteness of reporting allows that an individual may not have been included in the survey
 - d. lack of sensitivity of the information in question means that publication reveals no harmful information

6. procedures used to protect the confidentiality of records, disseminated data sets, and published tabulations and analyses
 - a. names or other personal identifiers are necessary in public health surveillance
 - 1) to follow up individuals for determination of subsequent health events
 - 2) to link data systems for additional information on individuals
 - 3) to rule out duplicate reporting
 - b. when names or other identifiers are used, problems can be minimized with use of protected or “scrambled” identifier
 - c. maintain record systems and separate files with identifiers in secure areas
 - d. identifying information can be destroyed once it has served its designated follow-up or linkage function
 - e. avoid collection of data that will not be used but may identify
 - f. precise data are rarely essential
 - 1) date of birth
 - 2) income in exact amounts
 - 3) residence by street address
 - g. analyses or tables with cells with small numbers in publications should be suppressed
 - 1) no table should include a row or column in which all cases are found in one cell
 - 2) the marginal total of any row or column should not be fewer than three
 - 3) no estimate should be based on fewer than three cases
 - 4) no estimates should be published if one case contributes more than 60% to that estimate

- 5) no characteristics of individuals should be identifiable by calculation from other tabulated data in the same or other data sets

F. Veracity

1. usually considered in the disclosure by investigators of the goals and uses of surveillance information
2. may be an ethical duty of surveillance subjects once they participate
3. deception by subjects may contribute to erroneous results and public health harm

G. Investigators and persons in subjects' social environments

1. may be ethical duty of surveillance officials to inform appropriate authorities if condition of surveillance subject might affect others
 - a. infectious disease
 - b. violent intentions
2. paternalistic social beneficence might justify the breach of confidentiality

H. Surveillance and the public health community

1. principles justifying broad access of information
 - a. enhances the quality of science by allowing reanalysis and confirmatory studies - thus potentially contributing to public welfare
 - b. expands knowledge by facilitating additional analyses - also potentiality contributing to public welfare



- c. reduces the burden of surveillance on subjects
- d. reduces the burden of surveillance on practitioners

- 2. some agencies have policies to protect researchers' primary use and control of data they collect

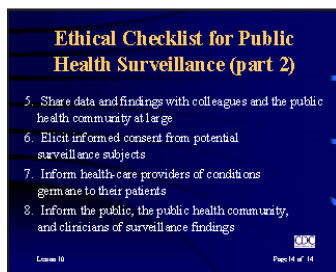
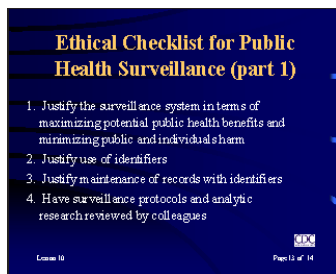
VI. Clinicians and the public health community

A. View of ethics

- 1. should not be regarded as an afterthought or an obstacle to professional practice
- 2. should be an element vital to the foundation and goals of professional practice

B. Ethical checklist for public health surveillance

- 1. justify the surveillance system in terms of maximizing potential public health benefits and minimizing public and individual harm
- 2. justify use of identifiers
- 3. justify maintenance of records with identifiers
- 4. have surveillance protocols and analytic research reviewed by colleagues
- 5. share data and findings with colleagues and the public health community at large



6. elicit informed consent from potential surveillance subjects
7. inform health-care providers of conditions germane to their patients
8. inform the public, the public health community, and clinicians of surveillance findings

C. Exercise:

- 1. form small groups*
- 2. have groups discuss potential ethical issues*
- 3. provide flip charts for groups to develop a short presentation*
- 4. have each group present to class*
- 5. facilitate further discussion*